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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/818,583 | 03/28/2001 | Hiroshi Tonoike | OKA-0025 | 3656 |

23353 7590 11/24/2003

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| EXAMINER | |
|---|---|
| KIM, YOUNG J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1637 | |

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/818,583 | TONOIKE, HIROSHI | |
| | Examiner | Art Unit | |
| | Young J. Kim | 1637 | |

*--The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --*

THE REPLY FILED 06 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet.*

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *1-11 and 13*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *12*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 1-6 and 11 under 35 U.S.C. 102(b) as being anticipated by Steiner et al. (Nucleic Acids Research, 1995, vol. 23, no. 13, pages 2569-2570), made in the Office Action mailed on August 7, 2003 is withdrawn in view of the arguments presented in the After Final Amendment received on November 6, 2003. Specifically, the Steiner rejection is withdrawn in view of the Applicants' statement indicating that the presence of PVPP in Steiner's' reference would "materially affect the basic and novel characteristic(s) of the claimed invention." (page 5, 2nd paragraph, Response). The instant specification discloses that reagents having an effect of agglutinating proteins have been used in the step of nucleic acid extraction (page 2, lines 22-24 of the specification) and that these purification procedures are inefficient and burdensome since they are time-consuming and involve complicated manipulations (page 5, 1st paragraph, Response). Based on this support, Applicants contend that PVPP is, "a kind of additive which has an effect of agglutinating proteins" and which is added to samples for "nucleic acid extraction" (page 5, 1st paragraph). Based on the support from the specification and Applicants' arguments, the presence of PVPP, an additive employed in the method of Steiner et al. would "materially affect the basic and novel characteristic(s) of the claimed invention," thereby being excluded from the instant method claims "consisting essentially of" the recited elements.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Di-San Junyi Daxue Xuebao, 1999, vol. 21, no. 1), made in the Office Action mailed on August 7, 2003 maintained for the reasons of record.

Applicants' arguments presented in the After Final Amendment received on November 6, 2003 have been fully considered but they are no found persuasive.
Applicants contend that the instantly claimed method allows for a "long period of time," a basic and novel characteristic not taught by the Liu et al. Applicants argue that because the method disclosed by Liu et al. allowed for some DNA degradation, such method would "materially affect" the basic and novel characteristic(s) of the claimed invention.
This argument is not found persuasive because Applicants' argument appears to indicate that none of the DNAs preserved through the Applicants' method were degraded (or damaged). Examiner is unaware of any preservation method in aqueous medium which does not allow for some degradation of DNA. The instant specification also fails to give any evidence to the contrary. Further, the method disclosed by Liu et al. is a preservation method. One of ordinary skill in the art would recognize that a preservation method would preserve a material to which the preservation is sought, for a time period. While Applicants' definition of the term, "long period" of time is vague since specification does not give an explicit time frame which an ordinarily skilled artisan would recognize as being "long," for the sake of argument, such period is considered to by that which was exemplified on page 13 (Example 2) - 10 months. Even based on this interpretation, Applicants have failed to successfully argue that the elements present in Liu et al. method would "materially affect" the basic and novel characteristics of the invention at hand. Initially, Applicants have failed to point out exactly what elements used Liu et al. would "materially affect" the instant claimed method. Secondly, Applicants also have failed to demonstrate that the preservation method of the instant application does not allow any degradation. Finally, if some degradation is to be expected, Applicants have not provided an evidence that the method of Liu et al. would not be able to preserve the DNA for 10 months (although it need not be 10 months based on explicit definition). According to In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964), "[i]f an applicant contends that the additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention." As discussed above, Applicants have failed to point out which "additional steps or components" would materially change the characteristics of Applicants' invention, nor have the Applicants provided evidence to the contrary which proves that: 1) instantly claimed method allows complete integrity of the element which is sought to be preserved (no degradation); or 2) the method disclosed by Liu et al. would not allow for storage of DNA for at least 10 months.

Finally, with regard to Applicants' statement that a "document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim (page 6, last paragraph, Response), Liu et al. explicitly teaches all of the limitations recited in the claim, that is, the method of storing a sample by homogenizing a living body-derived sample (whole blood) and a surfactant (SDS), then storing the homogenized sample (preservation method).

Therefore, Liu et al. anticipate the invention as claimed, and the rejection is maintained.

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

11/19/03

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